DETAILED ACTION

Response to Amendment

Amendment filed on 2/25/08 has been entered.

Claims 25-28, 30-31, 33-50 are present for examination.

Claims 1-24, 29, 32 are cancelled.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the **"an inflation branch angled with respect to said guide wire brand" of claim 45** must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

Claim 45 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the

specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation "a guide wire branch; and an inflation branched angled with respect to said guide wire branch" of claim 45 do not disclose anywhere in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25, 30-31, 33-34, 37 and 41are rejected under 35 U.S.C. 102(b) as being anticipated by Gharibadeh et al. (US 5,458,613).

Gharibadeh discloses a balloon dilation catheter comprising: a guide catheter10, a tubular member 11 having a proximal end and a distal end; an inflatable balloon 13 disposed at the distal end of the tubular member; a first lumen 12 disposed in the tubular member and in communication with an interior of the inflatable balloon; a second lumen 14, 20 disposed in the tubular member for receiving a guide wire 31, the second lumen having a first opening and a second opening at the distal end of the tubular member; a first slits (24, 26) disposed on tubular member; an adapter (33, 35) disposed at the proximal end of the tubular member; and an adapter slit (38, 39) disposed in the adapter; Fig. 3 clearly shows the slit to be narrow than the an outside diameter of the guide wire and Fig. 2 clearly shows the adapter slit being straight from a proximal end of the catheter to a proximal end of the adapter (see response to the Argument for details also); a third lumen is considered to be element 42 and a stiffening member considered to be the guide-wire/or metal wire 31.

Additionally, it is very well-known in the art to provide the adapter slit being straight from a proximal end of the catheter to a proximal end of the adapter. Examiner will provide the evidence if Applicant requests.

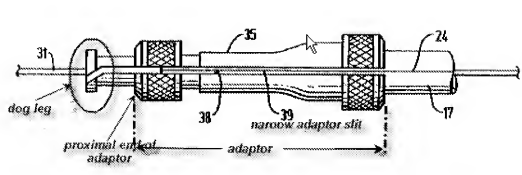

FIG. 2

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 26-28, 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gharibadeh et al. (US 5,458,613) in view of Schiffer (US 5,195,978).

Gharibadeh discloses the invention substantially as claimed. See above. Gharibadeh does not clearly disclose the first slit extends from the first opening to an area on the tubular member extends from the first opening to a second opening wherein the second opening is proximal to the inflatable balloon

Schiffer discloses a slit 32 extends from the first opening (located proximal 24) to the second opening (located distal end 26) (Figs. 1-3); wherein the second opening is proximal to the inflatable balloon.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Gharibadeh with the slit, as taught by Schiffer, in order to allow the physician to progressively expose and remove the guide wire from lumen in a simple and expeditious manner.

Regarding claim 35, Gharibadeh I in view of Schiffer disclose the invention substantially as claimed. See above. Gharibadeh discloses a radio opaque marker 40 on a tubular extension 20. However, they do not disclose a radiopaque marker on the tubular member 11. It is common knowledge in the prior art to place radiopaque markers on tubs in the analogous art of balloon catheters for the purpose of tracking the location of the specific sections of the catheter in the body.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gharibadeh as applied to claim 25 above, and further in view of Horzewski et al. (US 4,748,982).

Gharibadeh discloses the invention substantially as claimed. See above. Gharibadeh in view of Schiffer do not disclose; the tubular member having various densities to provide a decreasing stiffness from the proximal end to the distal end.

Horzewski discloses that the tubular member 12 having various densities to provide a decreasing stiffness from the proximal end to the distal end (col. 2, lines 30-35).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the balloon catheter of Gharibadeh, as taught by Horzewski, in order to achieve the desirable stiffness for the shaft.

Additionally, Horzewski also discloses the radio-opaque marker 27, 28 disposed on the tubular member 12.

Claims 38-41, 43, and 45-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gharibadeh as applied to claims 30-31, 33-34, 37 above, and in view of Barry (US 5,685,847).

Gharibadeh discloses the invention substantially as claimed. See rejection of claim 25 above. Gharibadeh do not disclose a stent mounted on the balloon. Barry teaches a balloon catheter for deploying a stent. It is well known in the art to use balloon catheter to deliver stents. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the balloon catheter of Gharibadeh, as taught by Barry, in order to deploy stents.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gharibadeh in view of Barry as applied to claims 38-39 above, and further in view of Horzewski et al. (US 4,748,982).

Similarly to rejection of claim 36, Gharibadeh in view of Barry discloses the invention substantially as claimed. See above. Gharibadeh in view of Barry do not disclose the tubular member having various densities to provide a decreasing stiffness from the proximal end to the distal end.

Horzewski discloses that the tubular member 12 having various densities to provide a decreasing stiffness from the proximal end to the distal end (col. 2, lines 30-35).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the balloon catheter of Gharibadeh in view of Barry, as taught by Horzewski, in order to achieve the desirable stiffness for the shaft.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gharibadeh in view of Barry, and St. Germain et al. (US 5,833,706).

Gharibadeh discloses the invention substantially as claimed. See rejection of claims 25 above. Gharibadeh does not disclose a stent mounted on the balloon. Gharibadeh discloses the third lumen having a stiffness member as a guide-wire, but does not clearly disclose that the stiffness member is non-guide-wire.

Barry teaches a balloon catheter for deploying a stent. It is well known in the art to use balloon catheter to deliver stent. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the balloon catheter of Gharibadeh, as taught by Barry, in order to deploy stent.

St. Germain discloses that a stiffening wire 42 being disposed inside the tubular or lumen of catheter (Figs. 1-5).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the balloon catheter of Gharibadeh, as taught by St. Germain, in order to provide additional support for the manipulation of the catheter.

Response to Arguments

Applicant's arguments filed 2/25/08 have been fully considered but they are not persuasive.

1. Applicant argues that the term "guidewire branch" and "inflation branch" are very well known to those of skill in the art, and are clearly depicted in the drawings.

In response, If Applicant thinks the term "guidewire branch" and "inflation branch" is very common to those of skill in the art. How come Applicant does not mention nor show in the drawing? Examiner requests that Applicant point out these terms/limitations.

2. Applicant argues that Gharibadeh discloses the adaptor slit clearly has a dog-leg like angle at the proximal end of the adaptor but Gharibadeh does not disclose the adaptor comprises a straight slit throughout the entire length of the adaptor from a proximal end of the catheter to a proximal end of the adapter.

In response, the adapter is considered to comprise of first and second arms 33 and 35. Because of the "comprising" languages it is considered to be an open-ended language and could comprise other elements. The insert 37 and its protruding elements is shown to be additional to the adapter. See col. 7, lines 5-10. Thus, the "dog-leg" which applicant is arguing is considered to not be part of the adapter but of the insert 37 which if secured is considered part of the catheter shaft. See Fig. 2 above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763